United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR SPAIN

December 10 through 19, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Spain's meat inspection system from December 10 through 19, 2001. The four establishments certified to export meat to the United States, and the laboratory that was analyzing field samples for residues, were audited. All four establishments were conducting processing operations.

The last audit of Spain's meat inspection system was conducted in March-April 2001. The same four establishments had been audited at that time.

The following concerns resulted from the previous audit:

- The HACCP plans in all four establishments had not adequately stated the procedures that the establishments would use to verify that the plans were being effectively implemented and the frequencies with which these procedures would be performed.

- MSC inspection officials in three establishments had not been adequately verifying the establishments' monitoring of critical control points and plant verification procedures.

- Inadequate pre-operational sanitation had been found in two establishments.

- Cross contamination and insanitary handling of product had been observed in two establishments.

- Containers for edible and inedible product had not been identified in three establish-0ments.

- Condemned product was not being denatured in three establishments.

At the time of this audit, Spain was exporting only cured pork products to the United States; meat of Spanish origin was under restriction because of the presence in Spain of Rinderpest, Hog Cholera, and Scrapie. Spain was also considered to have a substantial risk associated with BSE and Swine Vesicular Disease. All pork used in products for export to the US originated in establishments certified for U.S. export in Denmark, the Netherlands, and (in Est. 14) from Hungary. Meat also entered these establishments from other establishments within the EC, but none of this meat was used in U.S.-eligible product.

During the period between January 1 and September 30, Spain had exported 339,295 lbs. of pork products to the U.S. 10,641 lbs. from Est. 16 were retained at the U.S. port of entry for unsound condition (most of this product was accepted after sorting).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Spanish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed reviewing a selection of inspection records in Spain's meat inspection headquarters preceding the on-site visits. The third was an on-site visit to each exporting establishment. The fourth was an on-site visit to the government laboratory where analytical testing of field samples for the national residue testing program was performed and field samples from some establishments were cultured for the presence of microbiological contamination with *Listeria*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems, and (5) enforcement controls, including the testing program for *Listeria*. Spain's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

All four Establishments (13, 14, 16, and 20) certified to export to the United States were audited; all four were evaluated as acceptable. Details of audit findings, including compliance with the requirements for HACCP programs and SSOPs, and testing programs for *Listeria* are discussed later in this report.

As stated above, six concerns had been identified during the last audit of the Spanish meat inspection system, conducted in March-April 2001:

- *The HACCP plans in all four establishments had not adequately stated the procedures that the establishments would use to verify that the plans were being effectively implemented and the frequencies with which these procedures would be performed.* This had been corrected.

- *MSC inspection officials in three establishments had not been adequately verifying the establishments' monitoring of critical control points and plant verification procedures.* This had been corrected.

- *Inadequate pre-operational sanitation had been found in two establishments.* No pre-operational sanitation deficiencies were found during this new audit.

- *Cross contamination and insanitary handling of product had been observed in two establishments.* Personal hygiene was found to be deficient in one establishment. Details are enumerated in the Sanitation Controls section of this report.

- *Containers for edible and inedible product had not been identified in three establishments.* This had been corrected.

- *Condemned product was not being denatured in three establishments.* This had been corrected in two of the establishments. No denaturing of condemned meat scraps was done in Est. 16, but establishment officials stated that the small amount that was condemned was mixed together with other garbage, floor sweepings, etc. The FSIS auditor did not see this as a concern. Nevertheless, following a discussion of the denaturing issue, management officials voluntarily proposed placing a seal on the containers that were transported to the rendering company in the rendering company's vehicles).

The following concerns arose as a result of this new audit:

- In two establishments, additional hand-washing facilities were needed.

- In two establishments, unmarked chemicals were found in production areas.

Entrance Meeting

On December 10, an entrance meeting was held in the Madrid office of the *Ministerio De Sanidad Y Consumo* (MSC), and was attended by Dr. Oscar Gonzalez Gutiérrez-Solana, Deputy Director General of Foreign and Veterinary Health, Ministry of Health and Consumer Affairs (briefly); Dr. Margarita Garzón Rigau, Chief of the Official Veterinary Service, General Subdirectorate for External (State) Hygiene and Veterinary Affairs; Dr. Julia Navarro Perales, Technical Officer, Official Veterinary Service, General Subdirectorate for External (State) Hygiene and Veterinary Affairs; Dr. Diego Pazos, Sr. Agricultural Specialist, FAS, American Embassy Madrid; Mr. Mario Carbajo Vila, Interpreter. The FSIS auditor (hereinafter called "the Auditor" was Dr. Gary D. Bolstad, International Audit Staff Officer, USDA, FSIS. Topics of discussion included the following:

- Itinerary and lodging arrangements for the Auditor were finalized.

- The Auditor shared with the MSC officials the updated data collection instruments that would be employed for HACCP programs and SSOPs (and, for information, also those that FSIS employs for *Salmonella* and *E. coli* testing).

- Training programs for veterinarians assigned to establishments certified for U.S. export and those responsible for supervising them were discussed. Details are presented in the Government Oversight section later in this report.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Spain's inspection system in March-April 2001.

Prior to the on-site audits of establishments, certain central documents were examined in the office of the meat inspection headquarters, including official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed, and reports from supervisory visits to establishments certified as eligible to export to the United States.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The Auditor observed and evaluated the process.

Government Oversight

A meeting was held on December 12 in the offices of the Autonomous Region of La Rioja in Logroño to discuss the details of government oversight in Spain. In addition to the Auditor, the meeting was attended by Dr. Margarita Garzón Rigau, Chief of the Official Veterinary Service, General Subdirectorate for External (State) Hygiene and Veterinary Affairs; Dr. Alberto Román Clausin, Chief, Food Hygiene Section, Dept. of Health and Social Services, General Dept. of Health, Government of La Rioja; Dr. Juan-José Martínez, Area Supervisor for Meat; and Dr. Salvador Abaigar Beñalva, Area Supervisor for Milk Products and Restaurants. The following information was provided:

Management Structure

The central meat inspection authority, the Ministry of Health and Consumer Affairs (MSC); is located in the capital city of Madrid. Spain has 17 "Autonomous Regions" (ARs) in mainland Spain and two more in North Africa (Ceuta and Melilla). Some of these ARs have several Provinces; some do not. Two of the establishments (13 and 14) certified for U.S.

export were in the city of Toledo in the Castilla La Mancha AR; one (16) was in the city of Logroño in the La Rioja AR, and one (Est. 20) was in the city of Utiel in the AR of Valencia.

Each AR has a *Consejería de Sanidad, Dirección General de Salúd Publica y/o Consumo* (Ministry of Hygiene, General Department of Public Health and/or Consumer Protection). One of the subdivisions of this regional Ministry is the *Servicio Higiene Alimentos y Veterinaria Salud Pública* (Food Hygiene and Veterinary Public Health Service) which has the main responsibility for implementing the meat inspection controls within the AR.

In the ten regions that have two or more Provinces, there is a Provincial Delegation, with a Provincial Director and a Public Health Service; the latter also has subdepartments called *Areas de Salud (*Areas of Health). Each of these has a Veterinary Coordinator. Within the Areas of Health there are further subdivisions into *Zonas Básicas de Salud* (Health Zones), each of which has its own veterinary officials, both (1) Veterinary Inspectors of Slaughter Establishments and (2) Veterinary Inspectors of Meat Industries.

In the seven regions which are not subdivided into Provinces, the general structure of the meat inspection responsibility starts with its subdivision into *Areas de Salud (*Areas of Health), and the further organization is as above (without Provincial Directors of separate Public Health Services).

The central authority (the MSC in Madrid) has the responsibility for (1) oversight of the Autonomous Regions in which there are establishments that produce meat that is eligible for export to any other country and (2) (in cooperation with the Autonomous Regional officials) determining the responsibilities and duties of each official employee at each level. This supervision is carried out by a subdivision of the Central Administration, called the Sub-division General of Exterior Health and Veterinary Services, within which designated *técnicos* (veterinarians) are responsible for the supervision of the ARs, at least once per year, with the following mandated duties:

1. Conducting on-site visits to all establishments authorized to export to the United States,
2. Verifying and evaluating the supervision by of the responsible officials in the AR,
3. Verifying and evaluating the supervision of the Provincial Delegation, and
4. Verifying and evaluating the official veterinary oversight in each establishment.

Each Autonomous Region that contains an establishment authorized for U.S. export is responsible for the implementation and application of the system of meat inspection requirements for meat and meat products eligible for export to the U.S. These responsibilities include supervision of the entire system at least once per year, and consist of the following:

1. On-site visits to all establishments authorized to export its products to the U.S.,
2. Verifying and evaluating the supervision by the responsible officials of the Provincial Delegations, or Chiefs of the Districts, or Chiefs of the Areas of Health, or the

corresponding responsible officials (Provinces may have different titles for the person in this position of authority and responsibility), and
3. Verifying and evaluating the oversight by the veterinary inspection official in each establishment.

The *Responsables de Area* (Area Supervisors) of the Provincial Delegations (in the ARs that have two or more Provinces) or the Chiefs of the Districts or Areas of Health (in the ARs that are not subdivided into Provinces) or the corresponding responsible officials, supervise the entire system of meat inspection in the AR at least ten times per year. This supervision consists of:

1. On-site visits to each establishment authorized to export to the U.S. to verify the controls required and
2. Verification of the oversight by the veterinary inspection official in each establishment.

Thus, each establishment certified to export to the U.S. receives at least one supervisory visit per month, or at least twelve supervisory visits per year, at least one of which is performed by an official from the central MSC authority in Madrid, at least one by an upper-level official from the Autonomous Area, and at least ten by Area Supervisors or their equivalent.

The supervisory visits are documented through the use of an "Inspection Form for the Official Supervision of the Establishments Authorized for the United States." A copy of this Form was provided; it is very closely modeled after the FSIS Foreign Establishment Audit Form.

The responsibility for developing and implementing the residue control and species verification programs lies with the *Subdirección General de Sanidad Exterior y Veterinaria* (Subdivision General of Exterior Health and Veterinary Services).

Authority for Approval and Withdrawal of Approval of Establishments

If the management of an establishment wishes to be approved to export to the U.S., the Order 9065 of the Ministry of the President of April 4, 1995, applies. This Order "regulates the technical-sanitary conditions and the conditions of authorization applicable to those establishments for meat and meat products for exportation to the United States of America." The following steps are required:

1. The establishment submits an application to the MSC in Madrid.
2. The central authority requests that the responsible official of the AR conduct a review of the establishment to determine whether the establishment fulfills all the requirements specified in Order 9065 as well as in other legislative issuances (which include the requirements for HACCP programs, SSOPs, labeling, and additives and preservatives) and provide a report.
3. If this report is favorable, one or more representative(s) from the Central Authority in Madrid makes an on-site visit to verify that all requirements have been implemented.

4. If all is acceptable, a Resolution of Authorization is passed by both the General Director of the MSC in Madrid and the General Director of the Ministry of Agriculture, Fisheries, and Foods.

The list of approved establishment is updated and approved annually by Dr. Oscar Gonzalez, Deputy Director General of Foreign and Veterinary Health, Ministry of Health and Consumer Affairs.

The authority to suspend production or withdraw U.S. export approval rests with the General Directors of MSC and of the Ministry of Agriculture, Fisheries, and Foods.

Independence and Resources

In the AR of La Rioja, there is one Veterinary Inspector assigned to the establishment (16). He is supervised by the *Responsible de Area* (Area Supervisor) in the offices of the AR in Logroño. He is one of eight government officials in these offices.

All inspection personnel assigned to establishments approved to export to the U.S. are veterinarians and are full-time employees of the Autonomous Regions. They are not permitted to perform and any establishment-paid tasks in establishments where they perform official duties. No private-practice veterinarians or establishment-paid individuals may be hired as temporary or part-time government employees in any establishment approved to export to the U.S.

Reporting Channels

- The *Responsible de Area* (Area Supervisor) supervises the establishment activities and the performance of the Veterinarian-In-Charge in each U.S.-approved establishment. If the results are acceptable, one copy of his routine supervisory report goes to the establishment and one to the Veterinarian-In-Charge. If concerns with the establishment activities and/or the performance of the Veterinarian-In-Charge arise from his evaluation, then his report goes to the Section Chief of the Food Hygiene Section of the Autonomous Region. This Section Chief has the authority to take any action necessary at the establishment level. His actions are then reported to the central MSC authority in Madrid for review and evaluation.

- When the representative of the central MSC performs the "monthly" inspection of an establishment's systems (usually once per year), he/she includes an evaluation of all the inspection controls in that establishment; evaluation of the *supervision* of the inspection personnel in the establishment is accomplished by means of an evaluation of the *documentation* produced by the officials who have conducted the other internal reviews, including officials of the Autonomous Regions, in addition to an evaluation of the entire controls by the in-plant veterinarian.

- Since there are no slaughter establishments certified as eligible to export to the U.S., testing for generic *E. coli Salmonella* species is not required. Reports of positive (violative) microbiological tests for Listeria, which are performed at the *Centro Nacional de Alimentación* laboratory in Madrid, are sent by fax to the MSC in Madrid and to the Central Services of the AR.

- Reports of violative residue results (the testing is also performed at the *Centro Nacional de Alimentación* laboratory in Madrid) are sent by fax to the MSC in Madrid and to the Central Services of the AR.

- Results of non-compliances in the individual establishments are sent to the Section Chief of the Food Hygiene Section of the Autonomous Region. This Section Chief has the authority to take any action necessary at the establishment level. His actions are then reported to the central MSC authority in Madrid for review and evaluation.

Recruitment and Training

Inspection officials in the MSC are hired by the Central Authority. Inspection officials in each Autonomic Region are hired by the Autonomous Regional Authority in that AR. As stated above, the performances of the officials of the AR are routinely verified and evaluated by the MSC central authority.

The Autonomous Regional Authority has the responsibility to ensure that meat inspection officials at the plant level have the proper pre-employment training before being assigned to an establishment certified for export to the U.S.

Public-Health-Risk Measures

- For the purposes of *Listeria* testing, a lot is defined as 725 kg (1,595 lbs.) Sixteen samples are taken from each lot. If a public-health concern arises as a result of a positive *Listeria* test, the results are faxed immediately to the Area Supervisor in the AR, who then telephones the Veterinarian-In-Charge (VIC) in the establishment. The VIC identifies and retains the product in the positive lot and 32 further samples are taken and analyzed. If these results are negative, the product is released. If any of the follow-up samples are positive, the lot is condemned. In all establishments certified for export to the U.S., when samples are taken for *Listeria* testing, the lot is always retained until the results are known. All lots are tested for *Listeria* before they are permitted to leave an establishment for shipping to the U.S. In the event of a positive sample taken by the establishment, the establishment is required by law to inform the VIC immediately, and the above procedure is followed.

- If a public-health concern arises as a result of a positive *residue* test, the results are faxed immediately to the Area Supervisor in the AR, who then telephones the Veterinarian-In-Charge in the establishment. The VIC identifies and retains or rejects the affected lot(s)

of product, depending on the nature of the risk. There are provisions in the national legislation (Royal Decree 3252) for the recall of any product that presents a public-health risk.

At the time of this audit, according to information provided during the country entrance meeting, there was not an official, formal training program in place for inspection personnel. Several officials from the MSC central offices had attended the FSIS course for foreign meat inspection officials at the FSIS Training Center in College Station, Texas, and more were scheduled to attend the next session. Establishment-based inspection officials in establishments certified for U.S. export and in other exporting establishments were also attending courses organized by the Autonomous Regions regarding HACCP programs and microbiology. There were no specific courses regarding SSOPs *per se*, but cleaning programs and procedures were included in the courses. The National Health School, an autonomous institution belonging to the Ministry of Health also organized training courses for veterinary staff. The Veterinarian-In-Charge in Est. 14 had attended several courses in the past two years that included training in the principles and application of HACCP programs. The Veterinarian-In-Charge in Est. 16 had attended three HACCP courses, one in 1997, one in 1999, and one in 2000. The Veterinarian-In-Charge in Est. 20 had attended a specific 20-hour HACCP course organized by the government of the Autonomous Region of Valencia. The Veterinarian-In-Charge of Est. 13 was not available at the time of the audit of the establishment, but the MSC officials assured the Auditor that he had also had HACCP training.

Establishment Audits

Four establishments (Establishment numbers 13, 14, 16, and 20) were certified to export meat products to the United States at the time this audit was conducted; all four were audited on-site. Adequate MSC inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products: all of the establishments were evaluated as acceptable.

Laboratory Audit

The Institute De Salud Carlos 111, *Centro Nacional De Alimentacion* Laboratory in Majadahonda was audited on December 17, 2001, against the equivalent European Union Directive (EN 45001 guidelines).

During the laboratory audit, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

- Government oversight of accredited, approved, and private laboratories.

- Intra-laboratory quality assurance procedures, including sample handling.

- Methodology.

Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, check sample frequency, and corrective actions. The methods used for the analyses were acceptable.

Establishment Operations by Establishment Number

The following operations were being conducted in the four establishments:

Cured/dried pork products (Serrano ham) – two establishments (13 and 20)
Cured/dried chorizo sausage – one establishment (16)
Packing of Serrano ham – one establishment (14)

SANITATION CONTROLS

Based on the on-site audits of establishments, Spain's inspection system had effective controls in place for water potability records; chlorination procedures; back–siphonage prevention; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; product-contact equipment; dry storage areas; welfare facilities; personal dress; cross-contamination prevention; equipment sanitizing; and product handling, storage, reconditioning, and transportation. The following sanitation problems were identified:

- In two establishments, additional hand-washing facilities were needed: in Est. 13, there were no hand-washing facilities in a shipping area (exposed product was handled in this area), and in Est. 14, there was no hand-washing station in the room where hams were removed from the molds. The establishment management officials gave assurances of prompt correction.

- Several edible product workers in Est. 16 were observed to touch their faces with their hands and protective gloves without washing them before continuing to work with the product. MSC officials ordered corrective actions.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program: the SSOPs were found to meet the basic FSIS regulatory requirements. The data collection instrument used accompanies this report (Attachment A).

ANIMAL DISEASE CONTROLS

Spain's inspection system had controls in place to ensure adequate product identification, restricted product control, and procedures for sanitary handling of returned and rework product. No Spanish slaughter establishments were approved for export to the United States at the time of this audit. All hog carcasses or hams used for product exported to the United States were imported from slaughter establishments certified to export to the United States in Denmark, the Netherlands, and Hungary.

No outbreaks of animal diseases with public-health significance had been reported since the previous U.S. audit. Spain had had thirty positive cases for Bovine Spongiform Encephalopathy (BSE) and had been declared free of Foot-and-Mouth Disease. Spain was considered to have a substantial risk associated with BSE and Swine Vesicular Disease. APHIS had not declared Spain free of Rinderpest, hog cholera, and Scrapie.

RESIDUE CONTROLS

Spain's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Spanish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and use of chemicals. One problem was identified:

- In two establishments, unmarked chemicals were found in production areas. Establishment management officials took immediate corrective actions.

The National Program for Residue Control was based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC April 1996) and the control of residues on live animals and animal products (Council Directive 96/23/EC of April 1996). These directives had been transposed into Spanish law through the Royal Decree No. 1749 in 1998.

The establishments were required to submit a certain number of samples to the laboratory. The number of samples to be analyzed for each class of compounds depended upon the volume of product exported to the United States. At the export volume in effect at the time of this audit, two samples were randomly selected per month from the samples submitted by Est. 14, one from Est. 16 for residues and two for species verification, and one from Est. 20. The laboratory then randomly selected which analyses were to be run on those samples. No samples had been submitted from Est. 13, since no new raw product had been received since the previous FSIS audit. Two samples for each class of compounds, selected at random by the head of the residue program (Dr. Sánchez, the Deputy Director of the laboratory), were analyzed per month from one of the three establishments (also selected at random) receiving new raw product.

SLAUGHTER/PROCESSING CONTROLS

The Spanish inspection system had controls in place to ensure adequate pre-boning trim, ingredients identification, control of restricted ingredients, formulations, packaging materials, processing schedules, processing equipment, and processing records. Additionally, establishments had adequate controls in place to prevent meat products intended for Spanish domestic consumption from being commingled with products eligible for export to the United States.

No slaughter establishments in Spain were certified as eligible to export to the United States at the time of this audit.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system equivalent to that of the United States. Each establishment's HACCP system was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements. with one minor exception:

- The establishment individual responsible for the HACCP program in Est. 20 had not attended a formal training course in the principles of HACCP, but had studied specific materials, most of which were provided by central MSC authority, and also some by the government of the Autonomous Region of Valencia; he also had obtained further materials on the Internet. Note: The HACCP program was in full compliance.

Testing for Generic *E. coli*

Spain did not slaughter beef or pork for export to the U.S., and no ground meat was produced in establishments certified for U.S. export; thus, *E. coli* testing was not required. It was noted that generic *E. coli* testing was being conducted on ready-to-eat products in Est. 20. All hams intended for export to the United States were imported from slaughter establishments approved to export to the United States in Denmark, the Netherlands, and Hungary.

Control of *Listeria monocytogenes*

A sample of Pork Chorizo from Est.16 in Spain had tested positive for *Listeria monocytogenes* in October 2001 at a port of entry in Florida. The American Embassy in Madrid received the first notice from FSIS on Nov. 20 and notified the MSC officials on Nov. 23. The message was stamped as having been received on Nov 26. MSC officials sent an answering report to the Embassy on Friday, Dec. 7.

In Establishments 14 and 16, samples were being taken from each lot shipped to the U.S. (approx. 700-kg in each lot) – this had been the standard procedure for at least the previous two years. No product had been shipped to the US since the positive sample in Florida while the investigation was continuing. The packaging area was being investigated in particular. Some 1,000 samples had been taken altogether; two positives were found in April 2001 and one on Sept. 5, 2001,) in the final product before packaging. A follow-up set of 32 samples was taken from the Sept. 5, 2001, product that had tested positive; all results were negative. That lot was then released for shipment to the U.S. The positive sample in Florida was NOT from this same lot. Multiple samples of final packaged product had also been analyzed in the lab in Majadahonda; there had been no positives.

In Est. 20, eight samples were taken monthly for laboratory testing; testing for *Listeria* was one of the analyses performed. The samples were sent to the reference laboratory in Majadahonda. The laboratory randomly selected the analyses that it would perform on the samples from this establishment. In calendar year 2001, for example, samples were analyzed for *Listeria* in January, February, March, April, July, and November. The processing of Serrano hams takes one year; no product leaves an establishment before the results of analysis are made known (the results were available within two weeks of sampling). One sample, taken April 23, 2001, was positive for Listeria. The entire lot of 1,290 hams was (and, at the time of this audit, still was) retained. Two or three months before the drying processing is complete, five samples from the product were to be analyzed again. If all five samples are negative for *Listeria*, the product would be released.

Samples of product from Est. 13 (where the Serrano hams were only dry-cured) were taken and submitted in Est. 14, from which they were shipped. No fresh product entered Est. 13: the product that was eligible for the U.S. (there was none in the establishment at the time of the audit) was salted at the sister establishment (14) in Torrijos.

Inspection officials in Est. 14 were taking 12 samples of product at reception and two further samples after processing, on packaged product, monthly. All product was retained pending receipt of the results. In the event of a positive test for *Listeria,* the entire lot was condemned.

ENFORCEMENT CONTROLS

Inspection System Controls

The MSC inspection system controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. These included control of restricted product and inspection samples, processed meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls, inspection supervision, and documentation, and the importation of only eligible meat products from other counties (i.e., only from eligible countries and certified establishments within those countries), for further

processing. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Regional authorities provided information that residue violations are followed up on a case-by-case approach depending upon the substance in question. At the farm, the autonomous government will increase inspections but may not take a sample every time. Intensified sampling is statistically based, and if over half of the samples are positive, the entire herd will be destroyed. If the substance is prohibited, there are criminal sanctions resulting in arrest and possible fines and/or incarceration.

The Veterinarian-In-Charge of Est. 16 had attended three formal courses in the principles of HACCP in 1997, 1999, and 2000. The Veterinarian-In-Charge of Est. 14 had attended several courses in HACCP, the latest in June 2001; this last course was developed and presented by the Council of Health of the Autonomous Region of Castilla-La Mancha in the facilities of the University of Toledo. The Veterinarian-In-Charge in Est. 20 had attended a specific 20-hour HACCP course organized by the government of the Autonomous Region of Valencia. The Veterinarian-In-Charge of Est. 13 was not available for the audit of the establishment, but the MSC officials assured the Auditor that he also had HACCP training, and provided documentation to support this.

Testing for *Salmonella* Species

Spain did not slaughter beef or pork for export to the U.S., and no ground meat was produced in establishments certified for U.S. export; thus, *Salmonella* testing was not required. It was noted that *Salmonella* testing was being conducted on ready-to-eat products in Ests.14, 16, and 20. All hams processed for export to the United States were imported from slaughter establishments approved to export to the United States in Denmark, the Netherlands, and Hungary.

Species Verification

At the time of this audit, Spain was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

In Est. 16, the Veterinarian-In-Charge was taking two samples per month of the final product (chorizo) for species evaluation.

Monthly Reviews

Each establishment certified to export to the United States, whether actively engaged in producing for the U.S. market or not, received a minimum of one internal review per month. The internal reviews in Spain were being conducted in three parts as follows:

1. A representative of the MSC central authority (either Dr. Margarita Garzon Rigau or Dr. Julia Navarro Perales, both of whom were veterinarians in the Ministerio de Sanidad y Consumo, under the direct supervision of the *Subdirector General de Sanidad Exterior y Veterinaria*, Dr. Oscar Gonzalez Gutiérrez-Solana) conducted one of the monthly visits each year.

   No specific method was used for selecting the review dates of the establishments, but the dates varied from year to year. The internal review program was applied only to export establishments. These internal reviews were announced to the inspection personnel about two weeks in advance. Copies of each internal review report were maintained on file in the establishment and in the head offices of the *Ministerio de Sanidad y Consumo* in Madrid.

2. A staff veterinarian of the Autonomus Government Public Health office also conducted one internal review per year. Copies of each internal review report were maintained on file in the establishment and in the Autonomus Government Public Health office.

3. The remaining ten reviews per year were performed by staff veterinarians of the Provincial Governments. No specific method was used for selecting the review dates of the establishments, but the dates varied from each review. Copies of the internal review reports were kept in the Provincial headquarters and in the establishments. They were being maintained on file for a minimum of 3 years.

   The internal review program by the Provincial Governments was applied only to export establishments. The internal reviews were announced to the inspection personnel, about two weeks in advance; the establishment officials were not informed in advance. The records of reviewed establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the provincial offices.

If an establishment failed to comply with U.S. requirements during an internal review, it would be immediately delisted for U.S. export. Before it may again qualify for eligibility to be reinstated, MSC meat inspection officials are empowered to conduct an in-depth review, and the results would be reported to Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General de Sanidad Exterior y Veterinaria, for evaluation. He would formulate a plan for corrective actions and preventive measures.

Further details of these programs are provided in the Government Oversight section, earlier in this report.

Enforcement Activities

Dr. Oscar Gonzalez Guitars Solana, Subdirector General, MSC, referred to Royal Decrees # 1904 and 1993, which empower meat inspection officials to enforce noncompliance when

they determine that an establishment does not meet the regulatory requirements. Under these decrees, MSC may temporarily withhold the marks of inspection from specific products, suspend inspection, or withdraw a grant of inspection if an establishment is not meeting crucial requirements.

Exit Meetings

An exit meeting was conducted in Madrid on December 19, 2001. The participants were Dr. Margarita Garzón Rigau, Chief of the Official Veterinary Service, General Subdirectorate for External (State) Hygiene and Veterinary Affairs; Dr. Julia Navarro Perales, Technical Officer, Official Veterinary Service, General Subdirectorate for External (State) Hygiene and Veterinary Affairs; Dr. Marta García López, Chief, Inspection Section, Subdirectorate of Animal Health, Ministry of Agriculture; Mr. Antonio Garcia Jane, Chief, Food Hygiene Section, General Directorate of Public Health, Dept. of Health, Autonomous Regions of Castilla and La Mancha; Ms. Visitacion Cortes Ibañez, Chief, Management Section, General Directorate of Public Health, Autonomous Region of Valencia; Dr. José J. Sánchez Sáes, Subdirector of the National Food Center Laboratory; Mr. Clemente Garcia Gonzales, Veterinary Inspector-In-Charge of Est. 16; Dr. Diego Pazos, Sr. Agricultural Specialist, FAS, American Embassy Madrid; Mr. Mario Carbajo Vila, Interpreter; and Dr. Gary D. Bolstad, International Audit Staff Officer, USDA, FSIS.

The deficiencies identified (insufficient hand-washing facilities, unmarked chemicals, and deficient personal hygiene), were discussed in detail. The Spanish officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site reviews of each establishment, and stated that they would ensure implementation of the corrective actions.

A second meeting was conducted with European Commission (EC) officials in Brussels, Belgium on December 21, 2001. The participants were Dr. Paolo M. Drostby, EC Expert, Unit E-3, Directorate-General for Health and Consumer Protection; Dr. Javier Alcázar Sirvent, Permanent Representative of Spain to the EC; Ms. Caroline Hommez, Staff Officer, Foreign Agricultural Service, United States Mission to the European Union in Brussels; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The findings of the audit of Spain were reiterated and discussed.

CONCLUSION

The four establishments certified by Spain as eligible to export meat products to the United States and the government residue testing laboratory were audited: all were acceptable.

A great deal of effort had gone into correcting the deficiencies identified during the previous FSIS audit in March-April 2001, and—with the sole exception of several instances of poor personal hygiene practices—all had been adequately addressed and resolved. The very few deficiencies encountered during the on-site establishment audits were adequately addressed

to the Auditor's satisfaction. The MSC meat inspection officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site audits of each establishment, and stated that they would ensure prompt and continued compliance.

Dr. Gary D. Bolstad (signed)Dr. Gary D. Bolstad
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing *(not applicable)*
D. Data collection instrument for *Salmonella* testing *(not applicable)*
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
13	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√
16	√	√	√	√	√	√	√	√
20	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards ident-ified	4. Use & users includ-ed	5. Plan for each hazard	6. CCPs for all hazards	7. Mon-itorin g is spec-ified	8. Corr. actions are des-cribed	9. Plan valida-ted	10.Ade-quate verific. Proced-ures	11.Ade-quate docu-mentation	12. Dated and signed
13	√	√	√	√	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√	√	√	√	√
16	√	√	√	√	√	√	√	√	√	√	√	√
20	√	√	√	√	√	√	√	√	√	√	√	√